

ENAMEL plus[®] Flow Stain

(EN) ENGLISH

Enamel plus Flow Stain is a light curing composite for dental restorations.

Enamel plus Fluorescent Flow Stain is a system of light curing stains made of composite for the characterisation of composite.

Introductory kit COSSTAINKIT contains:

-6 light curing stains: White, Yellow, Orange, Blue, Brown, Brown 2 (Dark brown)

-6 brushes: C, F, M (2 per type)

Composition

- MONOMER MATRIX: Diurethane dimethacrylate, Bis-GMA, Tetramethylene dimethacrylate.

- TOTAL CONTENT OF FILLERS: 46% weight (34% volume) inorganic fillers (0,005 - 3,0 µm)

Also available separately: Red, Violet, Transparent and Black with different composition

Monomer matrix: Diurethane dimethacrylate, Tetramethylene dimethacrylate

TOTAL CONTENT OF FILLERS: 77% weight (57% volume) inorganic fillers (0,005 - 40 µm)

Indications

Characterisation of composite materials in dental office and laboratory.

Precautions

Contains tetramethylene dimethacrylate

Warning: May cause an allergic skin reaction. Wear protective gloves/protective clothing/eye protection/face protection. If skin irritation or rash occurs: Get medical advice/attention.

Contra-indications

If a patient has known hypersensitivities towards a component of this product, we recommend not to use it or to do so only under strict medical supervision. In such cases, we will supply the composition of our medical device upon request. The dentist should consider known interactions and crossreactions of the product with other materials already in the patient's mouth before using the product.

Side effects

With proper use of this medical device, unwanted side-effects are extremely rare. Reactions of the immune system (allergies) or local discomfort, however, cannot be ruled out completely. Should you learn about unwanted side-effects – even if it is doubtful that the side-effect has been caused by our product – please kindly contact us.

To prevent possible reactions of the pulp in cavities where the dentin is exposed, the pulp must be protected adequately (apply e. g. a calcium hydroxide preparation).

Materials to be avoided

Materials containing phenolics (like eugenol) could inhibit composite curing. Avoid the use of these materials as liners.

DOSAGE AND DIRECTIONS FOR USE

APPLICATION OF STAINS

Take Enamel plus FLOW STAIN out from syringes using the application needles and apply it, using Ena C brush. The M brush is suggested for composite application and smoothing, while the F brush was developed for the fossa carving.

Be careful during the light curing stains application because of colour intensity and material fluidity. It is possible to use stains mixed with composite bodies for shoulder and dentin. You can obtain the individualisation of the composite mixing, applying or introducing colours. When handling the material be careful not to create bubbles.

Layer-thickness: Apply a very thin layer of Enamel plus FLOW STAIN (no more than 0,3 mm for dark shades).

Please note

- When placing time consuming restorations, to prevent the composite curing prematurely the dental light should be moved away from the working site temporarily or the composite should be covered with foil impervious to light.
- For hygienic reasons, the curved application tips supplied with the material must only be used once!
- Use a light polymerization system with an emission range of 350 – 500 nm to polymerize the material. The required physical properties are only reached if the polymerization light functions properly. Therefore, it is necessary to check the light intensity regularly according to the manufacturer's instructions.

Curing information

Dental office curing units:

We recommend regular LED-curing units having a light intensity of around 1200 mW/cm². The intensity must not be reduced below 650 mW/cm² (= minimum intensity).

Dental office curing times:

- | | |
|------------------------|-----------------------|
| - Blue Phase (Ivoclar) | min. 40 sec per layer |
| - CLED2 (Micerium) | min. 40 sec per layer |

Laboratory curing units:

The required physical results can be reached only if using a multi-wall reflecting unit.

Laboratory curing times:

- | | |
|------------------------|------------------|
| - LABORLUX3 (MICERIUM) | approx. 90 sec.* |
|------------------------|------------------|

- Hilite (Kulzer) approx. 180-270 sec.*
 - Spektramat (Ivoclar) approx. 1 min*
 - LampadaplusT with light 71- 86 W (Micerium) approx. 10 min
- *for light colours. For dark colours until 3-5 min required

Disinfection / Protection from cross-contamination

Place the syringe with the application tip attached into a suitably shaped barrier sheath; pierce the end of the sheath, exposing the cannula for use. The use of a barrier sheath facilitates cleaning and disinfection of the syringe between patients.

After use, hold the tip through the sheath; unscrew and remove the tip along with the sheath. Dispose of the used tip and the sheath through the appropriate waste stream. Place the cap on the syringe again screwing it.

Disinfection - After removing the application tip and the sheath, disinfect the syringe using an intermediate-level disinfection process (liquid contact) as recommended by the Centre for Disease Control and endorsed by the American Dental Association. Guidelines for Infection Control in Dental Health-Care Settings - 2003 (Vol.52; No. RR-17), Centre for Disease Control and Prevention (USA).

USE AND STORAGE

Store between 3°C (38°F) and 25°C (77°F).

Do not use the product after the expiration date (see label on syringe).

Due to hygienic reasons flow application needles should be used only once.

Use the material at room temperature. Push back the spindle after taking out the material, to avoid an outflow of the material.

After use, close container with cap and keep it closed. Avoid direct exposure to sunlight.

Medical device, for dental use only by dentists and dental technicians: keep away from children.

This product was developed specifically for the described range of applications. It must be used as described in the instructions. The manufacturer is not liable for damage caused by handling or processing the material incorrectly.

Troubleshooting

Trouble	Cause	Remedy
Flow Stain does not cure	Luminous intensity of the polymerization unit insufficient	Check luminous intensity; replace light source, if necessary
	Emitted spectral range of the polymerization unit insufficient	Consult manufacturer of polymerization unit; recommended spectral range: 350 – 500 nm
Flow Stain seems to be too hard/ firm inside the syringe	Material was stored at temperatures below 3°C for a longer period of time	Let composite reach room temperature before use
	Syringe was not closed tightly which caused part of the material to cure	Close syringe correctly with the cap after each use
Stain Flow does not cure sufficiently	Layer thickness per polymerization cycle too high	Keep to max. layer thickness of 0,3 mm



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